

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 30

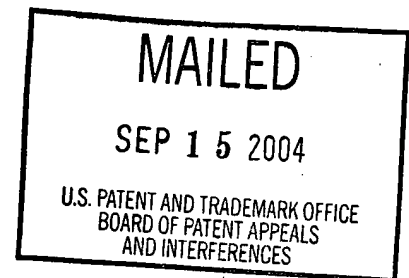
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte BERND FABRY

Appeal No. 2004-0762
Application No. 09/554,387

ON BRIEF



Before WINTERS, GRIMES, and GREEN, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 11 through 30, which are all of the claims remaining in the application.

Representative Claims

Claims 11, 17, 21, 27, and 30, which are illustrative of the subject matter on appeal, read as follows:

11. A method of reducing serum cholesterol content in a mammal, said method comprising:

(i) providing a hypocholesteremic preparation comprising at least one component (a) selected from the group consisting of phytosterols and phytosterol esters and at least one component (b) selected from conjugated fatty acids having from about 6 to about 24 carbon atoms and glycerides of conjugated fatty acids having from about 6 to 24 carbon atoms; and

(ii) administering the hypocholesteremic preparation to a mammal in an amount effective to reduce serum cholesterol content in the mammal.

17. The method according to claim 11, wherein the at least one component (b) comprises conjugated linoleic acid.

21. A hypocholesteremic preparation comprising at least one component (a) selected from the group consisting of phytosterols and phytosterol esters and at least one component (b) selected from conjugated fatty acids having from about 6 to about 24 carbon atoms and glycerides of conjugated fatty acids having from about 6 to about 24 carbon atoms.

27. The hypocholesteremic preparation according to claim 21, wherein the at least one component (b) comprises conjugated linoleic acid.

30. The hypocholesteremic preparation according to claim 21, wherein the hypocholesteremic preparation is combined with a foodstuff.

The Prior Art References

In rejecting the appealed claims on prior art grounds, the examiner relies on the following references:

Jandacek	3,865,939	Feb. 11, 1975
Hidvegi	5,277,910	Jan. 11, 1994
Miettinen et al. (Miettinen) (European Patent Specification)	EP 0 594,612 B1	Aug. 6, 1997

Hasegawa et al. (Hasegawa), "Cholesterol Decreasing Effect of Linoleic Acid and Plant Sterol (Report 1) Fluctuations in Serum Lipids in Healthy Males," Women's Nutrition College Bulletin, Vol. 14, pp. 165-172 (1983)

The Rejection

Claims 11 through 30 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combined disclosures of Jandacek, Hasegawa, Miettinen, and Hidvegi.

Deliberations

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including all of the claims on appeal; (2) applicant's Appeal Brief (Paper No. 23) and the Reply Brief (Paper No. 25); (3) the Final Rejection (Paper No. 16) and the Examiner's Answer (Paper No. 24); and (4) the above-cited prior art references.

On consideration of the record, including the above-listed materials, we reverse the examiner's prior art rejection.

Discussion

In setting forth the rejection of claims 11 through 30 under 35 U.S.C. § 103(a), the examiner relies on the combined disclosures of Jandacek, Miettinen, Hasegawa, and Hidvegi. As pointed out by applicant, however, the examiner has not established that any of those references discloses or suggests "at least one component (b)" recited in the appealed claims, viz., "at least one component (b) selected from conjugated fatty acids having from about 6 to about 24 carbon atoms and glycerides of conjugated fatty

acids having from about 6 to about 24 carbon atoms" (emphasis added). Therefore, the examiner has not established that the combined disclosures of prior art references would have led a person having ordinary skill to the claimed invention.

The examiner presents two main lines of argument. First, according to the examiner, Jandacek broadly discloses the use of unsaturated fatty acids having from 6 to 18 carbon atoms. See Paper No. 16, page 3, lines 1 through 4 ("Jandacek teaches broadly the usefulness of phytosterols such as β -sitostenol along with saturated and unsaturated fatty acids having from 6 to 18 carbon atoms including any conjugated fatty acids having from 6 to 18 carbon atoms, e.g., conjugated linoleic acid, in the instant claimed method")(emphasis in original). By the same token, the examiner argues that Miettinen suggests "the combination of phytostenol esters and fatty acids broadly including linoleic acid, employed in the instant claimed method" (Paper No. 24, page 6, lines 15 through 17)(emphasis added). However, the examiner has not established that the relatively broad disclosures of Jandacek or Miettinen would have led a person having ordinary skill in the art to applicant's claimed subject matter requiring conjugated fatty acids having from about 6 to about 24 carbon atoms or glycerides of conjugated fatty acids having from about 6 to about 24 carbon atoms. As stated in the specification, page 4, lines 6 through 13:

Conjugated fatty acids

The term conjugated fatty acids is understood as meaning aliphatic carboxylic acids having 6 to 24, preferably 16 to 18, carbon atoms and at least two double bonds which are conjugated to one another, i.e. are separated by exactly one single bond. Typical examples are the conjugated linoleic acid (CLA) or conjugated fish fatty acids [emphasis added].

Although Jandacek discloses unsaturated fatty acids having 6 to 18 carbon atoms and Miettinen discloses fatty acids broadly, the examiner has not established that either of those references discloses or suggests conjugated fatty acids with the meaning ascribed in the specification, page 4, lines 6 through 13. Accordingly, we disagree with this line of argument. Cf. In re Jones, 958 F.2d 347, 349, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) ("We decline to extract from Merck [Merck & Co. v. Biocraft Labs., Inc.], 874 F.2d 804, 806-09, 10 USPQ2d 1843, 1845-48 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989)] the rule that the Solicitor appears to suggest -- that regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it").¹

Second, according to the examiner, Hasegawa discloses that an excellent cholesterol decreasing effect was obtained through a synergistic action between linoleic acid and sitosterol (Hasegawa, English translation, page 7, lines 7 through 9; Paper No. 24, page 5, lines 14 through 16). Likewise, the examiner argues that Hidvegi discloses a pharmaceutical composition for lowering the blood-lipid level containing sitosterol and fatty acids such as linoleic acid (Paper No. 24, page 6, lines 18 through 20). According to the examiner,

One of ordinary skill in the art would clearly recognize that the known structure of linoleic acid is substantially similar to the structure of conjugated linoleic acid because they are structural isomers which have two double bonds but merely differ in one position of one double bond. [Id., page 5, lines 18 through 21]

¹ We note that the specific solubilizing agents (acids) disclosed by Jandacek in Table I, bridging columns 3 and 4, are not conjugated fatty acids. Nor has the examiner established that rapeseed oil, disclosed by Miettinen at page 3, contains any conjugated fatty acids.

In other words, the examiner argues that the cited references would have led a person having ordinary skill in the art to a hypocholesteremic preparation comprising sitosterol and linoleic acid; that linoleic acid is "substantially similar" in structure compared with conjugated linoleic acid; and, accordingly, that the cited references would have led a person having ordinary skill in the art to a hypocholesteremic preparation comprising sitosterol and conjugated linoleic acid. We disagree.

As stated in In re Grabiak, 769 F.2d 729, 731, 226 USPQ 870, 872 (Fed. Cir. 1985), "generalization should be avoided insofar as specific chemical structures are alleged to be prima facie obvious one from the other." On the particular facts in Grabiak, the court found inadequate support in the prior art suggesting "the interchangeability of sulfur for oxygen in the ester moiety of the Howe molecule" (Id.).

As stated by the court:

The PTO cited no pertinent reference showing or suggesting to one of ordinary skill in the art the change of a thioester for an ester group. In the absence of such reference, there is inadequate support for the PTO's position that this modification would prima facie have been obvious. [Id.].

Like the situation presented in Grabiak, the examiner in this appeal does not cite any reference disclosing the art-recognized equivalence of linoleic acid and conjugated linoleic acid for the purpose of achieving a cholesterol lowering effect. In the absence

of prior art disclosing such art-recognized equivalence, there is inadequate support for the PTO's position that this modification would have been prima facie obvious. As stated in In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 177-78 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968), "The legal conclusion of obviousness must be supported by facts. Where the legal conclusion is not supported by facts it cannot stand." (Emphasis in original; footnote omitted)

On the record before us, we conclude that the examiner did not establish a prima facie case of obviousness, and did not shift the burden of persuasion to applicant to rebut any such prima facie case with objective evidence of non-obviousness. Accordingly, we find it unnecessary to discuss the "indicia of non-obviousness" set forth the specification, pages 8 and 9, and discussed in applicant's Appeal Brief, section II.

The examiner's decision, rejecting claims 11 through 30 under 35 U.S.C. § 103(a), is reversed.

Other Issue

As stated in In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980),

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art.

On return of this application, we recommend that the examiner re-evaluate the patentability of applicant's claims in light of the foregoing statement of law in Kerkhoven and the following discussion.

In the specification, page 4, lines 13 through 15, applicant states that "[i]t is known of conjugated linoleic acid that it has a low hypocholesteremic action." Although the record on this point has not been fully developed, nevertheless, it would appear that the foregoing statement constitutes acknowledged prior art. In other words, it appears that applicant would acknowledge that persons having ordinary skill recognized and understood, at the time the invention was made, that conjugated linoleic acid has hypocholesteremic activity. On return of this application to the Examining Corps, the examiner and applicant should clarify if, in fact, that is the case.

We consider now claim 21, the broadest claim in this application, which "reads on" a hypocholesteremic preparation comprising (a) a plant sterol or a plant sterol ester; and (b) conjugated linoleic acid. The record makes clear that plant sterols and plant sterol esters were known in the art as possessing hypocholesteremic activity at the time the invention was made. For example, see the acknowledged prior art in the instant specification, page 1, lines 18 through 21; Jandacek, column 1, lines 25 through 30; and Miettinen, page 2, lines 4 through 7. If, on reflection, the examiner ascertains that the statement in applicant's specification, page 4, lines 13 through 15, constitutes

acknowledged prior art, i.e., if it was known by persons having ordinary skill at the time the invention was made that conjugated linoleic acid has hypocholesteremic activity, it would follow that the aforementioned statement of law in In re Kerkhoven, 626 F.2d at 850, 205 USPQ at 1072, has applicability here.

Stated another way, if the statement in applicant's specification, page 4, lines 13 through 15, constitutes acknowledged prior art, the examiner should consider rejecting claim 21 under 35 U.S.C. § 103(a) for obviousness because "it is prima facie obvious to combine two compositions [plant sterols or plant sterol esters and conjugated linoleic acid] each of which is taught by the prior art to be useful for the same purpose [possessing hypocholesteremic activity], in order to form a third composition which is to be used for the very same purpose." We also recommend that the examiner engage in a claim-by-claim analysis, taking into account the foregoing discussion.

Further, on return of this application to the Examining Corps, we recommend that the examiner re-evaluate the patentability of applicant's claims in light of Hasegawa and the statement in applicant's specification, page 4, lines 13 through 15.

Hasegawa discloses that it was known, at the time the invention was made, that linoleic acid has hypocholesteremic activity (Hasegawa, English translation, page 1, Abstract, "Linoleic acid lowers the serum cholesterol levels"). If, on return of this application, the examiner determines that page 4, lines 13 through 15, of the

specification constitutes acknowledged prior art, such determination would establish that it was known to persons having ordinary skill that conjugated linoleic acid has hypocholesteremic activity. In other words, those facts would establish the art-recognized equivalence of linoleic acid and conjugated linoleic acid as hypocholesteremic agents.

Consider again Hasegawa's disclosure that "an excellent chol. decreasing effect was obtained through a synergistic action between linoleic acid and sitosterol" (Hasegawa, English translation, page 7, lines 7 through 9). Given (1) the cholesterol decreasing effect obtained by the combination of linoleic acid and sitosterol, and (2) the art-recognized equivalence of linoleic acid and conjugated linoleic acid as hypocholesteremic agents (if established by the examiner), it would appear obvious to persons having ordinary skill to substitute conjugated linoleic acid for linoleic acid in the combination of ingredients disclosed by Hasegawa, English translation, page 7, lines 7 through 9. For this reason too, we recommend that the examiner re-evaluate the patentability of claim 21 for obviousness. Likewise, we recommend a claim-by-claim analysis with the foregoing discussion in mind.

In conclusion, we reverse the examiner's rejection of claims 11 through 30 under 35 U.S.C. § 103(a) based on a combination of references. On return of this application, we recommend that the examiner re-evaluate the patentability of applicant's claims in light of our discussion in the "Other Issue" section of this opinion.

REVERSED

Sherman D. Winters
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

Lora Green
Administrative Patent Judge

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Cognis Corporation
Patent Department
300 Brookside Avenue
Ambler, PA 19002

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